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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,787	07/15/2003	John Simard	51300-00006	1118

45200 7590 02/22/2006  
PRESTON GATES & ELLIS LLP  
1900 MAIN STREET, SUITE 600  
IRVINE, CA 92614-7319

EXAMINER

HURT, SHARON L

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/620,787	<b>Applicant(s)</b> SIMARD ET AL.	
	<b>Examiner</b> Sharon Hurt	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 7-11, 18-26, are drawn to a polypeptide comprising external immunogens of membrane-associated proteins of **variola major**, classified in class 435, subclass 91.33.
- II. Claims 1-2, 7-11, 18-26, are drawn to a polypeptide comprising external immunogens of membrane-associated proteins of immunologically cross-reactive poxvirus, **vaccinia virus**, classified in class 435, subclass 91.33.
- III. Claims 3-6, are drawn to an isolated nucleic acid encoding the polypeptide of **variola major**, classified in class 435, subclass 91.1.
- IV. Claims 3-6, are drawn to an isolated nucleic acid encoding the polypeptide of immunologically cross-reactive poxvirus, **vaccinia virus**, classified in class 435, subclass 91.1.
- V. Claim 12 and 13 are drawn to a method of inducing an antibody response to **variola major**, comprising administering the polypeptide to a mammal, classified in class 424, subclass 9.34.
- VI. Claim 12 and 13 are drawn to a method of inducing an antibody response to immunologically cross-reactive poxvirus, **vaccinia virus**, comprising administering the polypeptide to a mammal, classified in class 424, subclass 9.34.

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- VII. Claim 13, is drawn to a method of inducing an antibody response comprising administering the immunogenic composition, comprising a nucleic acid to **variola major**, to a mammal, classified in class 424, subclass 9.2.
- VIII. Claim 13, is drawn to a method of inducing an antibody response comprising administering the immunogenic composition, comprising a nucleic acid to immunologically cross-reactive poxvirus, **vaccinia virus**, to a mammal, classified in class 424, subclass 9.2.
- IX. Claims 14-17, are drawn to a method of making an immunogen , classified in class 424, subclass 134.1.

For each of invention sets I-IX above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of **inventions I-IX and one of inventions A-L.**

- A. M1R
- B. A36R
- C. 15R
- D. B7R
- E. F8L
- F. A30L
- G. L1R
- H. A33R
- I. H5R
- J. B5R
- K. D8L

L. A27L

Inventions A-L are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, may represent structurally different polyproteins. Therefore, where structural identity is required, such as for immunogenicity, the different sequences have different effects.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different viruses having different functions and effects. The polyproteins can be used for producing different immunogens.

Inventions III-IV and I-II are unrelated. The invention in Group III and IV are a nucleic acid encoding the polyprotein of Group I and II. The nucleic acid can be used in a materially different process because it can be used for virus detection by hybridization methods.

Inventions I-IV, and V-IX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in

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a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polyprotein can be used in a materially different process such as an ELISA assay to detect infection in a subject.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for Groups I and II is not required for Groups IV-VI, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Housel James can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 7, 2006

  
2/29/06  
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